PD6 Exh 2

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HENRY SCHEIN®

Building a regulatory compliance program for the future: DEA Suspicious Order Monitoring and Human Tissue

April 17, 2014

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April 17, 2014

Len David
Henry Schein Inc.
135 Duryea Road
Melville, NY 11747

Dear Mr. David,

We are pleased to present our proposal to assist Henry Schein (HSI) on the Suspicious Order Monitoring (SOM) and Human Tissue (HT) projects. We understand that these are important initiatives to help HSI understand if it is effectively and efficiently addressing current regulatory risk. This proposal is focused on providing the details regarding our point of view, the project approach and our team. We believe our proposal highlights the differentiators we bring which are summarized below:

- Previous experience working with HSI in regulatory area, which provides us with an understanding and appreciation of HSI's unique culture and challenges.
- A highly focused, highly specialized team of professionals carefully selected to bring together deep subject matter specialists, extensive industry experience and prior knowledge of HSI.
- A project designed to accomplish the task at hand efficiently, but also be easily repeatable as other regulatory or compliance challenge areas emerge allowing Henry Schein to build their internal optimization capabilities for future regulatory obligations

It goes without saying that we are very excited about the possibility of continuing to work with Henry Schein. On behalf of our team, thank you for inviting Deloitte* to present our proposal, and we hope to have the honor of serving you. Please note that if there are areas in our quote where you feel that our response is unclear or not fully responsive to your questions, we would be happy to clarify it.

Sincerely,
Deloitte & Touche LLP

Seth Whitelaw
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Executive Summary

Our Understanding

Henry Schein is a leading supplier of healthcare products and services to office based dental, medical and veterinary service providers. Over the past few years HSI has Henry Schein has enhanced its compliance function but wants to understand whether those enhancements have effectively and efficiently addressed current regulatory risk specific to SOM and HT.

Our Approach

Our approach to assessing certain HSIs compliance functions will harness the DMAIC methodology to assess current state SOM and HT, identify relevant gaps in those processes and operations, and create a prioritized list of recommendations as well as a roadmap for implementation of agreed to recommendations .

Highlights from our DMAIC approach

Define	Measure	Analyze	Improve	Control
Establish a project charter, develop initial hypotheses and agree what will be measured	Review data and documentation and conduct analyses to further assess current state performance and identify gaps	Formulate recommendations to address root cause issues	Analyze, develop and refine implementation playbook with key stakeholders	***Out of scope*** ***Monitor metrics and continue to make improvements or corrective actions***

Anticipated Benefits for Henry Schein

- Providing a window into whether HSI's regulatory and compliance enhancements have effectively helped mitigate the risks inherent in working with controlled substances and human tissue.
- Reducing regulatory risk and identifying potential areas of continuous improvement
- Creating an effective, efficient and easily repeatable assessment process that will assist HSI to examine other priority areas of regulatory or compliance risk.

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Our Understanding of the Support Request

Henry Schein's Situation

- In business since 1932, Henry Schein has achieved growth in recent years, including rapid international expansion (operations in 20 countries and distribution to more than 200).
- The company continues to face increased regulatory risk from rapid organic growth, expanding global operations, intensified regulatory enforcement in addition to managing complex and varying regulatory requirements at federal, state, and international levels.
- Henry Schein has enhanced its compliance function but wants to understand whether those enhancements have effectively and efficiently addressed certain current regulatory risk.

Request for Support

Henry Schein is requesting support to:

1. Conduct an assessment of the DEA-mandated Know Your Customer/SOM processes and operations.
2. Simultaneously conduct an assessment of HT handling processes and operations.
3. Identify gaps in those processes and operations.
4. Create a prioritized list of recommendations as well as a roadmap for implementation of agreed to recommendations in each area that fits with the Henry Schein culture to help facilitate adoption and success.

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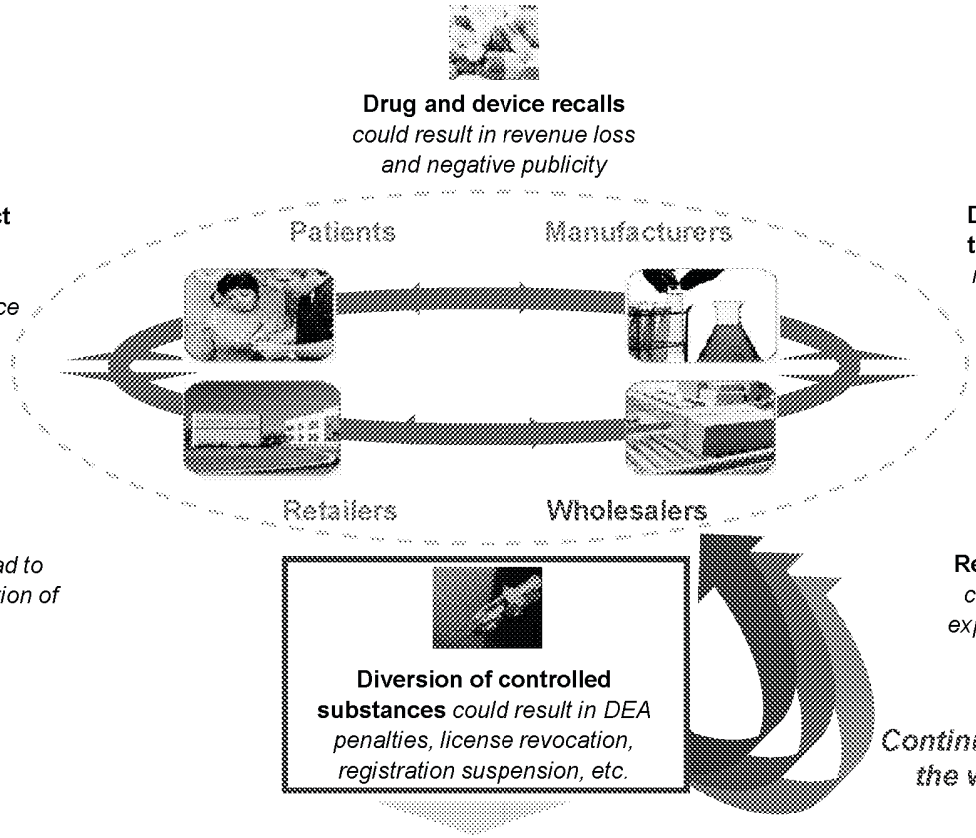
Pharmaceutical Supply Chain Risk



- Although the DEA has expanded its scrutiny to others, they continue to **focus on the wholesaler for the "policing"** of the sales and distribution of controlled substances
- In the last few years, DEA has cracked down on all **major drug wholesalers** issuing subpoenas, levying multi-million dollar penalties and prohibiting a few DCs from supplying controlled substances
- Numerous **drug retailers and pharmacy chains** have been investigated and a few of them have been permanently banned from shipping controlled substances. In some cases, hefty fines were imposed and sensitive documents were seized

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Deloitte has experience in designing and implementing SOM Programs

Large Pharmaceutical Distributor

Situation
The DEA revoked licenses for numerous client distribution centers and levied fines for the client's failure meet the SOM regulatory requirements. The client needed assistance in designing and executing a process to detect and report suspicious pharmaceutical orders of controlled substances. The client tasked Deloitte with managing the various project work threads, preparing the organization for audits, and leading implementation across all company business units,

Deloitte's approach
• Deloitte utilized project management tools and processes to guide and monitor the execution of the suspicious order program to each customer channel. • The team provided industry perspective in developing analytical approaches based on objective evidence to segment the client's customers into categories for valid statistical analysis • The team used proven training techniques and managed the training across all employees in the distribution centers and in the corporate organization • The team worked with the Client Communications group to develop on-line training, web updates, company updates and external presentations

Results
• Implemented a new and improved monitoring program to ensure the integrity of the supply chain specific to controlled substances to all customers and channels over a 12 month period • Mitigated risk of potential future regulatory fines and restrictions (~$1Billion loss revenues in 6 months; multi-million dollar fines) • Positioned the client to take a leadership role in supply chain integrity

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Deloitte's proposed approach (for both SOM & HT)

Define → Measure → Analyze → Improve → Control

	Define	Measure	Analyze	Improve
SOM Only	1 Week (Max)	2 Weeks (Max)	2 Weeks (Max)	1 Week (Max)
SOM & HT	2 Weeks (Max)	3 Weeks (Max)	2 Weeks (Max)	1 Week (Max)

Key Activities

Define
- Confirm project objectives and desired future state with HS stakeholders in advance of kickoff
- Gather data and documentation
  - Existing policies, procedures and process maps
  - Relevant organization and technology data
  - Internal audit reports
  - Regulatory review reports
- Conduct interviews with key stakeholders to perform initial qualitative assessment of current state performance

Measure
- Review data and documentation
- Conduct analyses to further assess current state performance
- Draft and review risk and performance indicators
- Conduct overall current state gap assessment

Analyze
- Formulate recommendations to address root cause issues across areas such as:
  - Processes/procedures
  - Monitoring/analytics
  - Investigations
  - Reporting
- Conduct with HSI prioritization of recommendations
- Review and refine recommendations with HS Leadership Team and key stakeholders

Improve
- Develop implementation timeline, milestones, resources, roles/responsibilities and change management considerations for each recommendation
- Review and refine implementation playbook with key stakeholders
- Conduct knowledge transfer as appropriate to key stakeholders

Deliverables

Define
- Stakeholder interview summary highlighting trends and themes

Measure
- Current state assessment

Analyze
- Prioritize and refine recommendations

Improve
- Implementation playbook

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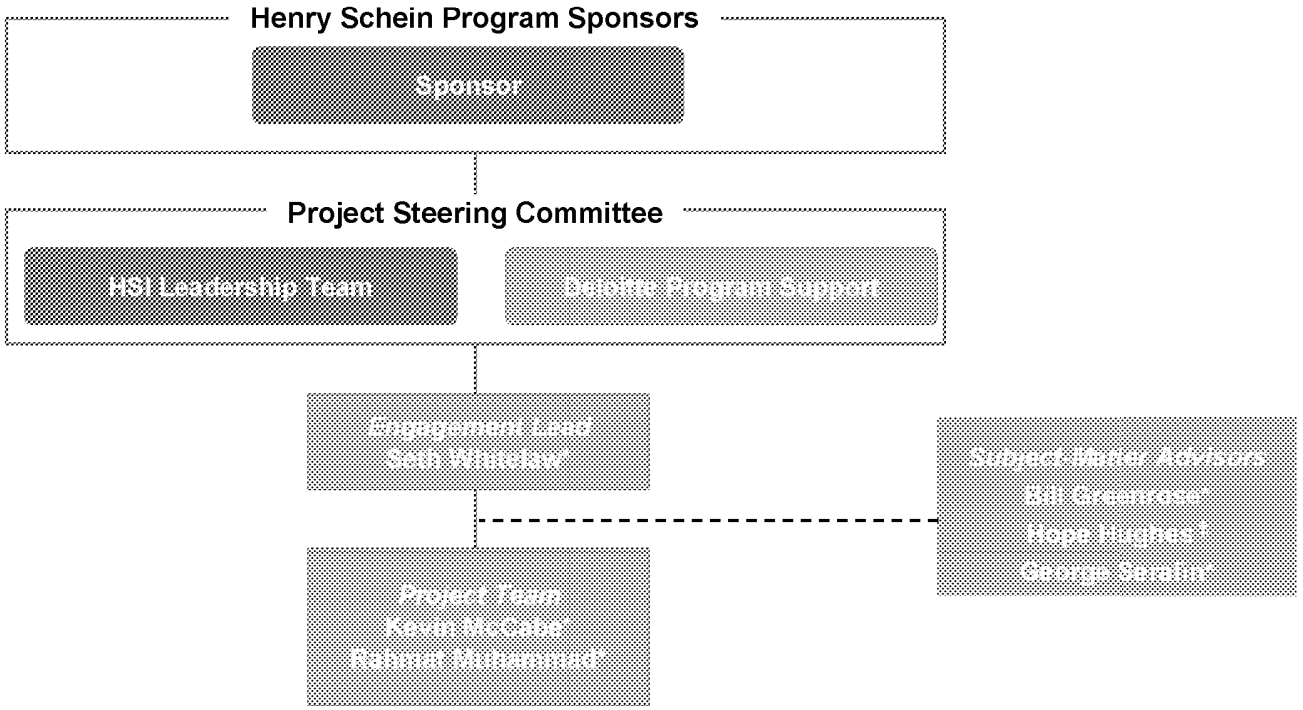
Proposed Project Team Structure

We are proposing a small, nimble and efficient project team that will leverage the broader breadth and experience of Deloitte while maintaining cost-effective results for Henry Schein.



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‡Monitor Deloitte Consulting

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Projected Project Hours

The inclusion of the Human Tissue option adds an additional 2 weeks duration and 196 project hours to the overall project

SOM Only (6 Weeks)

Project Role	Activities	Hours Per Week	Total Hours
HS Leadership Team & Stakeholders	• Interviews • Responding to Deloitte Project Team Questions • Review of draft deliverables and Weekly Status Updates	~ 3 (Maximum per individual)	18 (Maximum per individual)
Deloitte Project Team	Activities listed in the proposed approach	90 (Includes SMA time if utilized)	606

SOM and Human Tissue (8 Weeks)

Project Role	Activities	Hours Per Week	Total Hours
HS Leadership Team & Stakeholders	• Interviews • Responding to Deloitte Project Team Questions • Review of draft deliverables and Weekly Status Updates	~ 3 (Maximum per individual)	24 (Maximum per individual)
Deloitte Project Team	Activities listed in the proposed approach	90 (Includes SMA time if utilized)	802

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Key Project Assumptions

- Deloitte will conduct up to 10 interviews of approximately one hour duration for each phase of the project.
- In addition to work at Henry Schein Headquarters (Melville, NY), there will be one non-core site visit encompassing both SOM and Human Tissue
- Key stakeholders at the Headquarters and non-core sites will be available for interviews, project meetings, and to assist in gathering documentation (relevant policies and procedures, statistical models, IT user specifications, etc.)
- HSI will provide timely access to required personnel and data on an as-needed basis throughout the engagement via face-to-face discussion or telephone conversation. Deloitte also assumes that key HSI staff will work with our project team members.
- HSI will commit to timely decision-making and will provide timely resolution of project issues that affect the project plan and schedule. Unresolved issues could result in the project team's inability to meet the proposed schedule and result in increased costs and missed deadlines
- HSI shall provide the necessary logistics for the project, including facilities, supplies, telephone and data communications and other administrative matters necessary for the implementation of project activities

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The Deloitte Team

Backgrounds of the Deloitte team members

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Seth Whitelaw

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Experience

Seth has more than 20 years of experience in the life sciences and health care sectors in the areas of food and drug law and corporate governance, as well as designing and running compliance programs. He is a licensed food and drug attorney, with an doctorate in Health Law.

As an experienced Compliance officer, Seth has established and run three successful compliance programs for medical devices, pharmaceuticals sales and marketing and pharmaceuticals R&D. Most recently, he served as the compliance officer for GlaxoSmithKline R&D, where he established the global R&D compliance function for the newly merged companies of SmithKline Beecham, Inc. and Glaxo Wellcome, Inc. Included in his duties was the development of the R&D risk assessment and monitoring program and the establishment of R&D audit universe in conjunction with GSK Internal Audit and the oversight of the controlled substances program for GSK R&D. As part of that oversight, Seth has conducted numerous diversion investigations.

While at SmithKline Beecham, Inc. (SB), Seth established the compliance function for SB's North American sales and marketing operations. His duties included working with and training the field sale force, and educating sales and marketing leadership on appropriate regulatory and business conduct.

Prior to joining GSK, he also served as senior attorney and compliance coordinator for C. R. Bard, Inc., where he developed Bard's regulatory audit program as well as implementing and managing Bard's global compliance program in response to the *U.S. v. C.R. Bard, Inc.* settlement. This included undertaking several global diversion investigations. Finally, Seth also is a former Food and Drug Law Institute Fellow (FDLI) and also interned with the FDA's Office of Chief Counsel

Education

A.B. (Bowdoin College, Brunswick, ME)

J.D. (W&L University School of Law, Lexington, VA)

LL.M. (GWU Law School, Washington, D.C.)

S.J.D. (Widener University School of Law)

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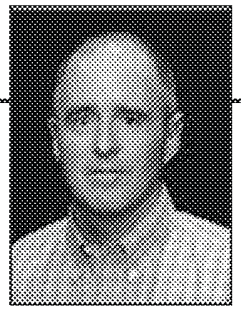
Kevin McCabe



Manager
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Experience

Kevin is a Manager in the Life Sciences regulatory consulting practice. He has over 13 years of experience in Pharmaceutical and Medical Device industries with extensive knowledge and experience regarding FDA and PDMA regulations, as well as PhRMA and AdvaMed Codes as they relate to pharmaceutical and medical devices companies. Kevin's background also includes conducting and directing fraud investigations, pharmaceutical promotional audits and investigations, promotional compliance, authoring and establishing governance documents and frameworks, training, and corporate security.

His client work has included a compliance organization assessment, a QA documentation review, authoring sample accountability and healthcare provider state license number/specialty validation procedures, and developing and executing a field force monitoring program. Additionally, he developed a governance document template for an energy sector client. His internal projects include establishing a Dodd-Frank Leadership Summit for energy sector clients and the development of a medical device security services offering.

Associations

Former member, PDMA Alliance Board of Directors

Education

MBA, Management (Monmouth University, West Long Branch, NJ)

BS, Psychology, (James Madison University, Harrisonburg, VA)

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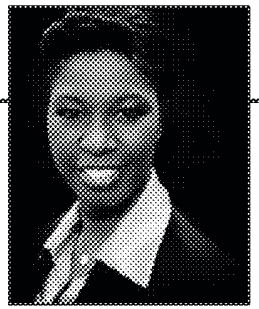
Rahmat Muhammad



Senior Consultant
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Experience

Rahmat Muhammad is a senior consultant within Deloitte's Life Sciences practice in the Northeast Region. Rahmat has over 10 years of consulting and industry experience in the Life Sciences and Consumer Product industries that includes performing hypothesis driven preclinical research, designing and developing tests of neural data to identify statistically significant patterns of brain activity, data mining government databases to identify trends in accidents associated with various products, and offering expert witness testimony in Federal and State courts. Most recently, she has supported clients in designing, developing, and implementing policy, process, and internal audit solutions to address business challenges faced by compliance, regulatory and risk functions and in identifying business risks and opportunities using strategic data analytics.

At Deloitte, Rahmat has served compliance organizations at leading medical device and diagnostics companies. She has assisted these clients to develop and implement global compliance strategies and tactical roadmaps to align with global healthcare payments transparency requirements. Her role in managing engagement activities includes drafting and tracking to high-level project plans and timelines across multiple activities, budget and resource allocation across activities, dependency definition between activities, tracking and escalation of challenges to resolution, process mapping, and business requirements definition for technical activities.

Education

Ph.D, Systems Neuroscience, MIT

B.A., Biology and Philosophy, Boston University

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George Serafin

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Experience

George Serafin is the National Practice Leader of Deloitte & Touche's Life Sciences and Healthcare Regulatory and Risk Consulting Practice. He has over 25 years of experience in the Life Sciences and Healthcare industries in the areas of R&D, engineering, manufacturing, supply chain, quality control/laboratory, quality assurance, regulatory, compliance, corporate/operations, and information technology.

With his broad and deep knowledge and "molecule to patient" perspective, George assists clients globally in developing and executing regulatory and risk strategies and remediation involving business process transformation, technology enablement, and advanced analytics across R&D, regulatory, manufacturing, post-market surveillance, and commercial operations.

George has demonstrated domestic and international regulatory compliance experience including CMS, DEA, EMEA, FDA, GCP/PV, GxP, HC, ICH, ISO, MHLW, MHRA, OIG, PDMA, 21 CFR Part 11, and PIC/S, including product submission/approvals, site registrations, 483/Warning Letter/Consent Decree and CIA response & remediation program development and execution.

Associations

ABET (Program Evaluator for Biomedical Engineering), American Society for Quality, Drug Information Association (Industry Advisory Board member), International Society for Pharmaceutical Engineering (GAMP Industry Advisory Board member), and the Parenteral Drug Association (Industry Advisory Board member)

Education

MA Science, Management of Technology (Stevens Institute of Technology, Hoboken, NJ)

BA Engineering, Biomedical Engineering (Stevens Institute of Technology, Hoboken, NJ)

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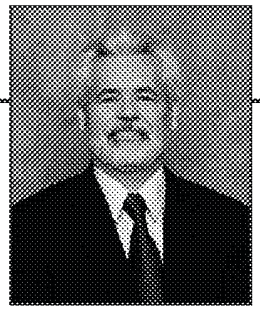
Bill Greenrose



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Experience

Bill Greenrose is a Director in Deloitte & Touche's Governance Regulatory and Risk Strategies practice. He has over 33 years of experience (23 in industry) in FDA and DEA regulated Life Science industries in the areas of compliance, regulatory, clinical, quality assurance, quality control, laboratory, R&D, manufacturing, core lab, and corporate/operations.

With his broad and deep knowledge and experience, Bill assists clients globally in developing strategies for compliance with relevant regulatory requirements (e.g. HIPAA, GxP, CE, CLIA, EPCS, "Know Your Customer", 21 CFR 1311), regulatory approach and submissions (e.g. pre-IDE, IDE, 510(k) PMA, CE Mark, Technical File), quality systems (e.g. QSR, GxP, ISO 13485, ISO 9001), regulatory compliance (proactive and reactive, e.g. Warning Letter/FDA 483 response), auditing and training in a highly regulated environment. Bill has helped companies develop, implement and revise programs for pre and post market commitment tracking as well as for PV, AEs and ADEs and has conducted many compliance gap assessments and training workshops. Having consulted for national and international pharmaceutical, medical device, and biotechnology companies, he is internationally recognized for his subject matter knowledge concerning regulatory compliance, quality systems, mobile medical devices, Internet-based data transmission, cloud deployment, DEA compliance and computerized systems validation (e.g. 21 CFR 11).

Associations

Regulatory Affairs Professional Society (RAPS), MassMEDIC, Drug Information Association

Education

MBA, Management (Fairleigh Dickinson University, Hackensack, NJ)

MA, Biology (Montclair University, Upper Montclair, NJ)

BS, Marine Science (Stockton State College, Pomona, NJ)

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Experience

Hope is a Director in Deloitte's Human Capital practice and works with clients to address the 'people dimension' of organization transformation. These large scale strategic change initiatives have included operating model and organization design, cost optimization programs, process redesign, risk and regulatory-related programs and technology implementations. With extensive experience leading strategic, complex engagements, Hope is focused on identifying and mitigating people-related risks that could jeopardize a program's success. Getting leaders aligned, involving the right people, communicating with transparency and authenticity, and building capabilities needed to sustain change are approaches used to drive adoption and capture value for clients.

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